



UNITED STATES PATENT AND TRADEMARK OFFICE

HL

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,967	12/31/2001	Wilhelmus Evergardu Hennink	313632001000	8024

7590 10/20/2004
Morrison & Foerster
2000 Pennsylvania Avenue NW
Washington, DC 20006-1888

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,967

Applicant(s)

HENNINK ET AL.

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1615

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 08/03/04. Claims 1-17 and 21-26 are pending.

Claim Rejections - 35 USC § 102

1. Claims 1-5, 7-10 and 13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Okihara et al. (J. Macromol. Sci. Phys. (1991) B30 (1 & 2) 119-140, submitted on form PTO-1449).

Applicants argue that Okihara does not disclose water-soluble or water-dispersible polymers and that the polymers of the prior art are not substituted with oligomers or co-oligomers. Applicants further state that the homopolymers of lactide are mostly insoluble in water; thus the Okihara reference cannot anticipate the claims because the polymers of Okihara are not water-soluble.

2. Applicants' arguments filed 08/03/04 have been fully considered but they are not persuasive.

Polymers of lactic acid and glycolic acid are water-soluble; at the worst they are sparingly soluble. Regarding the argument that the homopolymers of Okihara are not grafted to water-soluble polymer, it is noted that applicants rely on limitations that are not claimed. Applicants do not claim grafted polymer.

3. Claims 1-10, 14 and 21-26 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hennink et al. (WO 98/00170, cited on form PTO-1449).

Applicants argue that the instant polymers from mixture (A) interact noncovalently with polymers from mixture (B) while the polymers of the prior art are covalently attached.

Art Unit: 1615

Applicants further state that the polymers of the prior art are not water-soluble.

Applicants thus conclude that Hennink discloses water-soluble polymer containing oligomers that are partly formed from one chiral monomer and thus, the instant claims are not anticipated by Hennink.

4. Applicants' arguments filed 08/03/04 have been fully considered but they are not persuasive.

The instant claims do not exclude hydrolysable bonds consisting of two interpenetrating networks. Secondly, the disclosure by Hennink that (poly) glycolic acid and/or (poly) lactic acid spacers are incorporated between methacrylate groups and dextran does not specifically exclude chiral polymers. Hennink's polymers encompass both isomers since no specific isomer is stated. Thus Hennink does not exclude oligomers that are formed from the d- and l- monomers.

Claim Rejections - 35 USC § 103

5. Claim 11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hennink et al. (WO 98/00170).

Applicants argue that the rejection should be withdrawn because Hennink does not suggest or teach hydrogels containing polymers that interact noncovalently.

6. Applicants' arguments filed 08/03/04 have been fully considered but they are not persuasive.

It is noted that on page 6 of the response applicants indicate that oligomerized monomers are grafted to water-soluble polymer such as dextran and then applicants state in this section that the polymers of Hennink interact covalently. It is respectfully noted that the spacers, in this case

Art Unit: 1615

the lactide spacer is not interacting with the glycolide spacer. The lactide or glycolide is introduced between polymerizable methacrylate groups. Grafting involves breaking and making of bonds.

7. Claim 12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Okihara et al. (J. Macromol. Sci. Phys. (1991) B30 (1 & 2) 119-140, submitted on form PTO 1449).

Applicants argue that because claim 12 depend from claim 1, claim 12 is non-obvious over Okihara because Okihara's polymers are water insoluble.

8. Applicants' arguments filed 08/03/2004 have been fully considered but they are not persuasive.

Okihara's lactides/glycolides are water-soluble.

9. Claims 15-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over De Jong et al. (Macromolecules, 1998, 31:6397-6402, provided by applicants on form PTO-1449) in view of Brannon-Peppas (Int. J. Pharm, 1995, 116:1-9, provided by applicants on form PTO-1449).

Applicants argue that De Jong is silent regarding water-soluble or water-dispersible polymers and that the polymers of De Jong are not water-soluble polymers. Brannon does not remedy the deficiency of De Jong because the polymers of Brannon are not water-soluble.

10. Applicants' arguments filed 08/03/04 have been fully considered but they are not persuasive.

Regarding the sequence for preparing the drug containing hydrogel, selection of any order of the preparation steps in instant claims 15-17 is obvious in the absence of unexpected results showing the order recited in the instant claims to provide unexpected results. There is no demonstration that the recited order of steps provides unusual results. The lactides and

Art Unit: 1615

glycolides are water-soluble and thus De Jong and Brannon both disclose water-soluble polymers. Since lactides and glycolides are water-soluble, the prior art does not have to specifically state that the lactides and glycolides are water-soluble

No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 Blessing Fubara
Patent Examiner
Tech. Center 1600

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600